

Original Article

A Pilot Randomized Controlled Trial of a Holistic Needs Assessment Questionnaire in a Supportive and Palliative Care Service

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Abstract

Context. At present, there is no widely used systematic evidence-based holistic approach to assessment of patients' supportive and palliative care needs.

Objectives. To determine whether the use of a holistic needs assessment questionnaire, Sheffield Profile for Assessment and Referral for Care (SPARC), will lead to improved health care outcomes for patients referred to a palliative care service.

Methods. This was an open, pragmatic, randomized controlled trial. Patients ($n = 182$) referred to the palliative care service were randomized to receive SPARC at baseline ($n = 87$) or after a period of two weeks (waiting-list control $n = 95$). Primary outcome measure is the difference in score between Measure Yourself Concerns and Wellbeing (MYCAW) patient-nominated Concern 1 on the patient self-scoring visual analogue scale at baseline and the two-week follow-up. Secondary outcomes include difference in scores in the MYCAW, EuroQoL (EQ-5D), and Patient Enablement Instrument (PEI) scores at Weeks 2, 4, and 6.

Results. There was a significant association between change in MYCAW score and whether the patients were in the intervention or control group ($\chi^2_{trend} = 5.51$; degrees of freedom = 1; $P = 0.019$). A higher proportion of patients in the control group had an improvement in MYCAW score from baseline to Week 2: control (34 of 70 [48.6%]) vs. intervention (19 of 66 [28.8%]). There were no significant differences (no detectable effect) between the control and intervention groups in the scores for EQ-5D and Patient Enablement Instrument at 2-, 4-, or 6-week follow-up.

Conclusion. This trial result identifies a potential negative effect of SPARC in specialist palliative care services, raising questions that standardized holistic needs assessment questionnaires may be counterproductive if not integrated with a clinical assessment that informs the care plan. *J Pain Symptom Manage* 2015;50:587–598. © 2015 The Authors. Published by Elsevier Inc. on behalf of American Academy of Hospice and Palliative Medicine. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Key Words

Palliative care, holistic needs assessment questionnaire, SPARC, MYCAW, EQ-5D, PEI

Introduction

The Sheffield Profile for Assessment and Referral for Care (SPARC) ([Appendix I](#), available at jpsmjournal.com) is a multidimensional holistic needs assessment questionnaire, designed to identify patients who may benefit from additional supportive or palliative care, regardless of diagnosis or stage of

disease. SPARC is intended for use by primary care, hospital teams, or other services to improve patient management, either by current professional carers or by referral to a specialist team. The patient-rated (self-complete) 45-item questionnaire reflects nine dimensions of need and as such represents a comprehensive early needs assessment or holistic

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Table 1
Follow-Up Procedure

Questionnaire Completion (at 2-week intervals)	Randomization	
	Group A (Intervention Group)	Group B (Waiting-List Control Group)
Baseline	MYCAW, EQ-5D, PEI, SPARC	MYCAW, EQ-5D, PEI
Two weeks	MYCAW, EQ-5D, PEI [Invitation for patient interview]	MYCAW, EQ-5D, PEI, SPARC
Four weeks	MYCAW, EQ-5D, PEI plus supplementary question on experience of completing the SPARC	MYCAW, EQ-5D, PEI [Invitation for patient interview]
Six weeks	MYCAW, EQ-5D, PEI	MYCAW, EQ-5D, PEI plus supplementary question on experience of completing the SPARC
Eight weeks	Case note reviews Semistructured interviews with patients Semistructured interviews with health care professionals	

MYCAW = Measure Yourself Concerns and Wellbeing; EuroQoL (EQ-5D) = standardized outcome measure of health-related quality of life; PEI = Patient Enablement Instrument; SPARC = Sheffield Profile for Assessment and Referral for Care.

Those patients who consented were randomized to receive the SPARC questionnaire at baseline (intervention group) or after a two-week waiting-list period (control group).

questionnaire.¹ It is capable of being completed by patients unassisted, or, for those prevented by disability from reading or writing responses, with the help of their informal or professional carers.² Despite rigorous psychometric development, preliminary field testing, and validation,^{1–6} the clinical utility of SPARC has yet to be established, either as an aid to specialist clinical assessment or as a screening tool.⁷

There is evidence to suggest that patients with cancer and nonmalignant chronic progressive illnesses may experience distressing symptoms and concerns, which may remain unrecognized.^{7–10} Previous research has highlighted that distressing symptoms and concerns can be managed, provided they are identified in a timely manner and systems are in place for a prompt referral to specialist teams.^{11–16} The timely identification of needs and prompt referral to specialist teams could reduce the burden of suffering and lead to earlier discharge. Similarly, earlier detection of these problems in outpatients or the community might prevent unnecessary admissions. These potential health gains may accrue for a relatively small investment.⁷ However, at present, there is no widely used systematic evidence-based holistic approach to assessing patients for supportive and palliative care needs. There is a lack of studies on the clinical utility of tools.^{1,7}

We conducted a pilot pragmatic randomized controlled trial to determine whether the use of SPARC leads to improved health care outcomes (health-related quality of life and self-identified concerns) for patients referred to a palliative care service, to guide the development of a definitive multicenter study. This study represents a development of SPARC for use as an early holistic needs assessment questionnaire within a specialist service. This study does not test the utility of SPARC as a screening questionnaire for specialist palliative care. Palliative care interventions are complex, and in light of this, the SPARC study was developed, piloted, evaluated, reported,

and implemented in accordance with the Medical Research Council framework for developing and evaluating complex interventions (new guidance).^{17–19}

Methods

Trial Design and Recruitment

The trial is reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement²⁰ and was registered (International Standard Randomised Controlled Trials Number [ISRCTN] 25758268). This open randomized controlled trial used a waiting-list control design.²¹ All patients referred to the supportive and palliative care service who met the study inclusion criteria were invited to take part in the study. Invitations to participate were sent by post (outpatients and those in the community) or given face to face (inpatients and day care patients). Patients who consented to taking part in the study were randomized to receive the SPARC questionnaire at baseline (intervention group) or after a two-week period (control group).

The study received approval from the Bradford Research Ethics Committee, U.K. Multicentre Research Ethics Committee (MREC) reference number 10/H1302/88 on January 14, 2011 and received research and development permission from local trusts. Participants' inclusion criteria were 1) any diagnosis (cancer and noncancer), 2) any referral to the palliative care service in any care setting, 3) 18 years or older, and 4) able to give informed consent. Exclusion criteria included 1) incapable of giving informed consent, 2) incapable of completing SPARC even with the help of a relative or informal carer, and 3) younger than 18 years.

Stratification

Baseline quality of life may confound response to an intervention by reversion to the mean, so patients

Table 2
Research Questionnaires: Rationale for Choice of Outcome Measures

MYMOP	MYCAW Slightly Modified Version of MYCAW Used	EQ-5D	PEI Slightly Modified Version of PEI Used
<ul style="list-style-type: none"> ■ A precursor of MYCAW ■ Demonstrated sensitivity to change ■ Used in a range of contexts ■ Patient self-complete, outcome questionnaire, problem specific (includes general well-being) ■ Applicable to all symptomatic patients ■ Brief and simple questionnaire to administer ■ MYCAW used in preference to MYMOP because concerns raised could be of any kind and not restricted to symptoms or activity (may be of significance when comparing the information from the three groups: cancer survivors, people with long-term conditions, and people needing end-of-life care) ■ For the purposes of this study, it was important to use an outcome measure that covered the diversity in the patient group ■ A slightly modified version of MYCAW was used (the sentence "Please write down one or two concerns or problems which you would most like us to help you with" was replaced with "Please write down one or two concerns or problems that bother you most") <p>References: ^{24–26}</p>	<ul style="list-style-type: none"> ■ Developed from a validated tool, MYMOP, simple to use, and sensitive enough to show any changes with time ■ Patients nominate concerns, which may or may not be medical (MYCAW) or symptoms (MYMOP) of importance to them (two concerns/symptoms can be identified) ■ They then score these on a scale of 0 (not bothering me at all) to 6 (bothers me greatly) ■ Patients are also asked to rate their general feeling of well-being on a scale of 0 (as good as it could be) to 6 (as bad as it could be) ■ The follow-up form asks patients to rescore the concerns/symptoms and rate their general feeling of well-being they previously nominated, thus capturing any changes over time that are important to the patient ■ However, HRQoL may not be sensitive enough to changes in the short term, possibly because people adjust their expectations ■ Work by Guyatt et al.²⁷ indicates that in seven-point scales of this kind, a shift of one point corresponds to a moderately important change for a patient ■ Is an additional element of needs assessment, stated concerns, are truly patient generated, reflecting an accurate expression of need at that time <p>References: ^{25–27}</p>	<ul style="list-style-type: none"> ■ Outcome measure of health-related quality of life ■ Patient self-complete ■ Five questions (three varying response categories): on mobility, self-care, usual activities (e.g., work, study, housework, family, or leisure activities), pain/discomfort, and anxiety/depression ■ A further question (EQ-5D thermometer scale) asks people to mark their current health status on a scale of 0 (worst imaginable health state) to 100 (best imaginable health state) ■ Used extensively in studies where quality of life is compared between patient groups <p>References: ^{23,28}</p>	<ul style="list-style-type: none"> ■ Outcome measure of a patient's ability to cope with life and their illness and the confidence and ability to help themselves (as a result of visiting a doctor or health professional) ■ Patient self-complete ■ One main question "thinking about the last time you saw a doctor or nurse from palliative care, do you feel you are: ... (6 subquestions with four varying response categories)" ■ Studies in general practice to assess quality of consultations using PEI have shown it to be a crucial outcome measure, with enablement correlating best with the length of consultation and how well the patient knew the doctor ■ PEI scores consultations in cancer clinics, independently of quality of life and scores higher when sufficient time is allocated or when staff have communication skills training (our own unpublished work) ■ PEI may detect an effect of SPARC (if any) on the quality of subsequent consultations with the clinical team ■ A measure of consultation quality was included to detect an effect on communication between patients and professionals. However, we overestimated the intensity of contact between patients and professionals and palliative care services in the duration of this trial <p>References: ^{29,30}</p>

MYMOP = Measure Yourself Medical Outcomes Profile; MYCAW = Measure Yourself Concerns and Wellbeing; EuroQoL (EQ-5D) = standardized outcome measure of health-related quality of life; PEI = Patient Enablement Instrument; HRQoL = health-related quality of life.

were stratified for baseline EQ-5D (standardised outcome measure of health-related quality of life) thermometer score. Thus, patients completing the consent form also were asked to complete the EQ-5D thermometer score before randomization. Based on previous work,^{22,23} the research team set the EQ-5D thermometer score at 40. Patients scoring 40 or above at baseline were placed in the median and above group, and those scoring less than 40 were placed in the below median group.

Sheffield Palliative Care Service Context and Settings

Patients were recruited from the whole range of settings (inpatients, outpatients, day care, and from the

community), which included the two hospitals within the city, a palliative care unit, a hospice, and from the community via a team of community specialist nurses. More than 2000 patients a year are referred to these services, including those with long-term conditions and cancer survivors as well as those needing end-of-life care.

Intervention (SPARC)

Those patients who consented were randomized to receive the SPARC questionnaire (Table 1) at baseline (intervention group) or after a two-week waiting-list period (control group). All patients received ongoing care as usual. A completed paper copy of

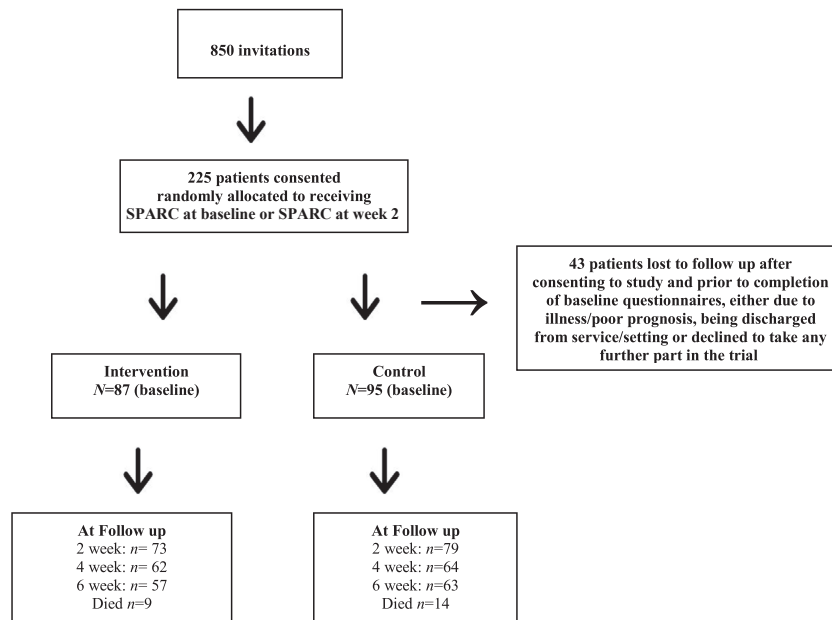


Fig. 1. Summary of recruitment for the Sheffield Profile for Assessment and Referral for Care (SPARC) trial. There was no significant difference in the number of deaths between the intervention and control groups. In Group A (intervention), nine people (10.3%) died within the eight-week study period and in Group B (control), 14 people (14.7%) died within the eight-week study period ($\chi^2 = 0.445$; degrees of freedom = 1; $P = 0.504$).

SPARC was sent to the health care professional (HCP) caring for the patient to prompt action on needs identified by SPARC. The SPARC questionnaire data also were kept in the patients' notes, and a copy was kept on the electronic clinical record. Follow-up study questionnaires were administered either face to face or by post. Two weeks was selected as the crucial follow-up time after baseline to minimize attrition.

Outcome Measures

Study participants were required to complete three validated brief self-complete research outcome measures: the Measure Yourself Concerns and Wellbeing (MYCAW), the EuroQoL (EQ-5D) (measure of health-related quality of life), and the Patient Enablement Instrument (PEI) at baseline, Week 2, Week 4, and Week 6 (Appendix II, available at jpsmjournal.com). The rationale for the choice of outcome measures is presented in Table 2.^{24–30}

The primary outcome was the change in MYCAW score between the first MYCAW patient-nominated concern at baseline and the two-week follow-up. This is the nominated first concern. Secondary outcomes included 1) the change in scores in the EQ-5D at the two time points; 2) changes in the PEI at the two time points; 3) comparisons of MYCAW patient-nominated concerns, EQ-5D, and the PEI at baseline between patient groups; and 4) the pattern of actions taken and referrals made as a result of administering the SPARC screening tool were

examined by analysis of the clinical record (to be reported elsewhere).

Randomization

A set of sequentially numbered, opaque, sealed, A4 envelopes containing all study documents were set up for each care setting (henceforth called the study pack). The randomization process was undertaken by a member of the study team (M.W.), who then identified which study packs were for the intervention arm and which were for the control arm. A copy of the SPARC questionnaire (Appendix I) was added to the study packs for the intervention arm, and 182 patients were randomized with computer-generated random numbers in prepaid sealed envelopes to receive SPARC at baseline ($n = 87$) or after a period of two weeks (waiting-list control $n = 95$).

Recruitment

For inpatients and day care patients, a HCP informed the patients about the study and asked whether they were willing to participate. Contact details of those patients willing to participate were passed to a member of the study team. Community patients and outpatients were sent study packs via medical secretaries (the list of patients was first agreed with the HCP with responsibility for the care of these patients). On receiving consent, the researcher (N.A.), who was blinded to the study, collected the next sequentially numbered, opaque, sealed envelope and hand delivered it to inpatients

Table 3
Baseline Demographic Characteristics of Participants in Group A (Intervention), Group B (Control), and Total Sample (A + B)

Characteristic	Intervention Group A (87)	Control Group B (95)	All Patients (182)	Notes A vs. B
	<i>n</i> (%)			<i>P</i>
Age (mean age in yrs) on registration	63.90 years (median = 65.00 years; SD = 11.68; minimum age = 28 years; maximum age = 87 years)	64.99 years (median = 67.00 years; SD = 13.34; minimum age = 27 years; maximum age = 90 years)	64.47 years (median = 66.00 years; SD = 12.57; minimum age = 27 years; maximum age = 90 years)	No significant difference (Mann-Whitney $Z = -0.865$; $P = 0.387$)
Gender				No significant difference ($\chi^2 = 1.183$; degrees of freedom = 1; $P = 0.277$)
Male	36 (41.4)	48 (50.5)	84 (46.2)	
Female	51 (58.6)	47 (49.5)	98 (53.8)	
Partnership/marital status				No significant difference ($\chi^2 = 1.706$; degrees of freedom = 3; $P = 0.636$). Most patients were married ($n = 118$; 64.8%)
Married	56 (64.4)	62 (65.3)	118 (64.8)	
Single	10 (11.5)	7 (7.4)	17 (9.3)	
Divorced/parted/separated	5 (5.7)	9 (9.5)	14 (7.7)	
Widowed	15 (17.2)	15 (15.8)	30 (16.5)	
Ethnicity				The low numbers in many of the groups meant that it was not possible to test for differences
White—British	83 (95.4)	90 (94.7)	173 (95.1)	
White—other background	2 (2.3)	0 (0)	2 (1.1)	
Black or Black British Caribbean	1 (1.1)	0 (0)	1 (0.5)	
Asian or Asian British-Indian	0 (0)	1 (1.1)	1 (0.5)	
Information withheld/not documented	1 (1.1)	4 (4.2)	5 (2.7)	
Living arrangements				Most patients were living at home ($n = 177$; 97.3%), three patients were living in a care or nursing home (1.6%), and for two patients (1.1%) it was not known where they were living
Home	83 (95.4)	94 (98.9)	177 (97.3)	
Care home/nursing home	3 (3.4)	0 (0)	3 (1.6)	
Patient lives alone				No significant difference in the proportions of patients living alone ($\chi^2 = 0.020$; degrees of freedom = 1; $P = 0.887$)
Living alone	15/73 (20.5)	20/88 (22.7)	35 (19.2)	
Religion				Most patients ($n = 115$; 63.2%) gave their religious denomination as Church of England
Church of England	56 (64.4)	59 (62.1)	115 (63.2)	
Roman Catholic	6 (6.9)	5 (5.3)	11 (6.0)	
Christian	5 (5.7)	7 (7.4)	12 (6.6)	
Jewish	2 (2.3)	2 (2.1)	4 (2.2)	
Methodist	3 (3.4)	4 (4.2)	7 (3.8)	
Protestant	1 (1.1)	1 (1.1)	2 (1.1)	
Humanist	1 (1.1)	0 (0)	1 (0.5)	
Anglican	1 (1.1)	0 (0)	1 (0.5)	
Agnostic	0 (0)	2 (2.1)	2 (1.1)	
Quaker	1 (1.1)	2 (2.1)	3 (1.6)	
Church of Scotland	1 (1.1)	0 (0)	1 (0.5)	
None	10 (11.5)	13 (13.7)	23 (12.6)	

or sent it via post to community patients and outpatients.

Statistical Methods and Analysis

Primary Endpoint Analysis. The primary outcome measure was the difference in score between the patient-nominated concern (MYCAW, Concern 1) on the self-scored visual analogue scale at baseline and at the two-week follow-up. Assuming the changes in the score (baseline to Week 2) would be normally distributed, we had planned to carry out a *t*-test to test the null hypothesis that the difference between the intervention and control groups in the mean score on the first symptom nominated on the scale at baseline and two weeks is 0. However, because the data were not normally distributed, the Mann-Whitney test was used to test for difference in the two groups in the rankings of Weeks 2, 4, and 6 scores and the rankings of the change in scores from baseline to Weeks 2, 4, and 6.

Statistical Power. To detect a medium-sized difference between two independent sample means at $\alpha = 0.05$ and $\beta = 0.80$, required a minimum of 64 individuals in each group with scores at baseline and two weeks.³¹ Therefore, a total of 128 patients would need to be recruited. The power of the study was based on the randomized controlled trial with the group of patients from whom it would be possible to obtain follow-up data. Differences between the control and intervention groups were tested using *t*-tests to compare the mean scores at Weeks 2, 4, 6, and the mean change in scores from baseline to Weeks 2, 4, and 6.

Secondary and Exploratory Analyses. Statistical analysis of the comparisons between patient groups for the secondary outcomes involved both descriptive analyses and statistical tests. A qualitative content analysis^{32,33} of the nominated first concern and the nominated second concern was undertaken at baseline. The concerns named in MYCAW were analyzed qualitatively using a summative content analysis approach. Stated concerns were examined for key words and themes, with the context taken into account for the final interpretation. Analysis of the data from patient semistructured interviews, HCP interviews,³⁴ case note reviews, and from the supplementary question about patients' experience of completing the SPARC will be presented elsewhere.

Results

Recruitment and Attrition Rates

A total of 850 patients were invited to take part in the study, of whom 225 consented to take part

Table 4
Distribution of Scores for MYCAW Concern 1 at Baseline and at 2-, 4-, and 6-Week Follow-Up in Group A (Intervention), Group B (Control), and for the Total Sample (Group A + Group B)

n (%)																				
MYCAW Concern 1 Score	Baseline						Week 2			Week 4			Week 6							
	A		B		Total	A		B		Total	A		B		Total	A		B		Total
	A	B	A	B	Total	A	B	A	B	Total	A	B	A	B	Total	A	B	Total		
0	2 (2.5)	3 (3.2)	5 (2.9)	2 (2.9)	4 (2.9)	3 (5.1)	6 (10.0)	9 (7.6)	2 (3.6)	3 (5.6)	5 (4.6)									
1	1 (1.2)	4 (4.3)	5 (2.9)	1 (1.4)	9 (6.5)	2 (3.4)	3 (5.0)	5 (4.2)	3 (5.5)	4 (7.4)	7 (6.4)									
2	6 (7.4)	6 (6.5)	12 (6.9)	6 (8.7)	17 (12.2)	4 (6.8)	4 (6.7)	8 (6.7)	4 (7.3)	4 (7.4)	8 (7.3)									
3	7 (8.6)	9 (9.7)	16 (9.2)	14 (20.3)	25 (18.0)	9 (15.3)	10 (16.7)	19 (16.0)	11 (20.0)	11 (20.4)	22 (20.2)									
4	20 (24.7)	20 (21.5)	40 (23.0)	13 (18.8)	24 (17.3)	14 (23.7)	14 (23.3)	28 (23.5)	9 (16.4)	15 (27.8)	24 (22.0)									
5	19 (23.5)	21 (22.6)	40 (23.0)	16 (23.2)	27 (19.4)	11 (18.6)	13 (21.7)	24 (20.2)	10 (18.2)	7 (13.0)	17 (15.6)									
6	26 (32.1)	30 (32.3)	56 (32.2)	17 (24.6)	33 (23.7)	16 (27.1)	10 (16.7)	26 (21.8)	16 (29.1)	10 (18.5)	26 (23.9)									
5																				
Total	81 (100)	93 (100)	174 (100)	69 (100)	139 (100)	59 (100)	60 (100)	119 (100)	55 (100)	54 (100)	109 (100)									

MYCAW = Measure Yourself Concerns and Wellbeing.

Table 5
Frequency of EQ-5D Responses in Groups A (Intervention) and B (Control) and Total Sample (A + B) at Baseline and Weeks 2, 4, and 6

Domain	Statement	Baseline Response, <i>n</i> (%)			Week 2 Response, <i>n</i> (%)			Week 4 Response, <i>n</i> (%)			Week 6 Response, <i>n</i> (%)		
		A	B	Total	A	B	Total	A	B	Total	A	B	Total
Group Mobility	I have no problems in walking about	13 (15.7)	9 (9.5)	22 (12.4)	11 (15.1)	10 (13.0)	21 (14.0)	10 (16.9)	8 (12.5)	18 (14.6)	8 (14.3)	5 (7.9)	13 (10.9)
	I have some problems in walking about	66 (79.5)	85 (89.5)	151 (84.8)	60 (82.2)	64 (83.1)	124 (82.7)	48 (81.4)	53 (82.8)	101 (82.1)	45 (80.4)	56 (88.9)	101 (55.5)
Self-care	I am confined to bed	4 (4.8)	1 (1.1)	5 (2.8)	2 (2.7)	3 (3.9)	5 (3.3)	1 (1.7)	3 (4.7)	4 (3.3)	3 (5.4)	2 (3.2)	5 (2.7)
	Total	83 (100)	95 (100)	178 (100)	73 (100)	77 (100)	150 (100)	59 (100)	64 (100)	123 (100)	56 (100)	63 (100)	119 (100)
	I have no problems with self-care	43 (53.1)	43 (45.3)	86 (48.9)	37 (51.4)	36 (46.8)	73 (49.0)	34 (57.6)	28 (44.4)	62 (50.8)	31 (55.4)	27 (42.9)	58 (48.7)
	I have some problems washing or dressing myself	33 (40.7)	48 (50.5)	81 (46.0)	31 (43.1)	36 (46.8)	67 (45.0)	22 (37.3)	33 (52.4)	55 (45.1)	20 (35.7)	33 (52.4)	53 (44.5)
	I am unable to wash or dress myself	5 (6.2)	4 (4.2)	9 (5.1)	4 (95.6)	5 (6.5)	9 (6.0)	3 (5.1)	2 (3.2)	5 (4.1)	5 (8.9)	3 (4.8)	8 (6.7)
Usual activities	Total	81 (100)	95 (100)	176 (100)	72 (100)	77 (100)	149 (100)	59 (100)	63 (100)	122 (100)	56 (100)	63 (100)	119 (100)
	I have no problems with performing my usual activities	7 (8.4)	6 (6.5)	13 (7.4)	7 (9.7)	8 (10.3)	15 (10.0)	3 (5.1)	8 (12.5)	11 (8.9)	4 (7.4)	7 (11.1)	11 (9.4)
	I have some problems with performing my usual activities	54 (65.1)	59 (63.4)	113 (64.2)	46 (63.9)	49 (62.8)	95 (63.3)	40 (67.8)	38 (59.4)	78 (63.4)	31 (57.4)	40 (63.5)	71 (60.7)
	I am unable to perform my usual activities	22 (26.5)	28 (30.1)	20 (28.4)	19 (26.4)	21 (26.9)	40 (26.7)	16 (27.1)	18 (28.1)	34 (27.6)	19 (35.2)	16 (25.4)	35 (29.9)
	Total	83 (100)	93 (100)	176 (100)	72 (100)	78 (100)	150 (100)	59 (100)	64 (100)	123 (100)	54 (100)	63 (100)	117 (100)
Pain/discomfort	I have no pain or discomfort	11 (13.3)	9 (9.8)	20 (11.4)	9 (12.5)	10 (13.2)	19 (12.8)	6 (10.3)	3 (4.8)	9 (7.5)	8 (14.8)	4 (6.6)	12 (10.4)
	I have moderate pain or discomfort	59 (71.1)	72 (78.3)	131 (74.9)	55 (76.4)	55 (72.4)	110 (74.3)	44 (75.9)	54 (87.1)	98 (81.7)	34 (63.0)	53 (86.9)	87 (75.7)
	I have extreme pain or discomfort	13 (15.7)	11 (12.0)	24 (13.7)	8 (11.1)	11 (14.5)	19 (12.8)	8 (13.8)	5 (8.1)	13 (10.8)	12 (22.2)	4 (6.6)	16 (13.9)
Anxiety/depression	Total	83 (100)	92 (100)	175 (100)	72 (100)	76 (100)	148 (100)	58 (100)	62 (100)	120 (100)	54 (100)	61 (100)	35 (29.9)
	I am not anxious or depressed	34 (42.0)	29 (31.9)	63 (36.6)	31 (43.1)	23 (29.9)	54 (36.2)	23 (40.4)	18 (29.0)	41 (34.5)	19 (34.5)	23 (37.7)	42 (36.2)
	I am moderately anxious or depressed	42 (51.9)	55 (60.4)	97 (56.4)	37 (51.4)	52 (67.5)	89 (59.7)	31 (54.4)	41 (66.1)	72 (60.5)	29 (52.7)	34 (55.7)	63 (54.3)
	I am extremely anxious or depressed	5 (6.2)	7 (7.7)	12 (7.0)	4 (5.6)	2 (2.6)	6 (4.0)	3 (5.3)	3 (4.8)	6 (5.0)	7 (12.7)	4 (6.6)	11 (9.5)
	Total	81 (100)	91 (100)	172 (100)	72 (100)	77 (100)	149 (100)	57 (100)	62 (100)	119 (100)	55 (100)	61 (100)	116 (100)

EuroQoL (EQ-5D) = standardized outcome measure of health-related quality of life.

Table 6
Distribution of PEI Responses in Groups A (Intervention) and B (Control) and Total Sample (A + B) at Baseline, Weeks 2, 4 and 6

Question	Response, <i>n</i> (%)	Baseline				Week 2	
		Group A (Intervention)	Group B (Control)	Total	<i>P</i>	Group A (Intervention)	Group B (Control)
Able to cope with life	Much better	8 (10.0)	8 (9.0)	16 (9.5)	0.301	4 (5.8)	9 (12.7)
	Better	32 (40.0)	28 (31.5)	60 (35.5)		22 (31.9)	16 (22.5)
	Same or less	40 (50.0)	53 (59.6)	93 (55.0)		43 (62.3)	46 (64.8)
	Total	80 (100)	89 (100)	169 (100)		69 (100)	71 (100)
Able to understand your illness	Much better	8 (10.8)	14 (15.9)	22 (13.6)	0.662	4 (6.3)	9 (13.0)
	Better	30 (40.5)	31 (35.2)	61 (37.7)		22 (34.4)	20 (29.0)
	Same or less	36 (48.6)	43 (48.9)	79 (48.8)		38 (59.4)	40 (58.0)
	Total	74 (100)	88 (100)	162 (100)		64 (100)	69 (100)
Able to cope with your illness	Much better	6 (7.8)	9 (10.0)	15 (9.0)	0.835	2 (3.0)	7 (10.1)
	Better	30 (39.0)	33 (36.7)	63 (37.7)		26 (38.8)	17 (24.6)
	Same or less	41 (53.2)	48 (53.3)	89 (53.3)		39 (58.2)	45 (65.2)
	Total	77 (100)	90 (100)	167 (100)		67 (100)	69 (100)
Able to keep yourself healthy	Much better	5 (7.1)	6 (7.1)	11 (7.1)	0.721	3 (4.8)	9 (14.1)
	Better	23 (32.9)	25 (29.4)	48 (31.0)		21 (33.3)	10 (15.6)
	Same or less	42 (60.0)	54 (63.5)	96 (61.9)		39 (61.9)	45 (70.3)
	Total	70 (100)	85 (100)	155 (100)		63 (100)	64 (100)
Confident about your health	Much more	2 (2.7)	3 (3.4)	5 (3.1)	0.687	3 (4.5)	5 (7.0)
	More	19 (25.7)	24 (27.6)	43 (26.7)		12 (18.2)	14 (19.7)
	Same or less	53 (71.6)	60 (69.0)	113 (70.2)		51 (77.3)	52 (73.2)
	Total	74 (100)	87 (100)	161 (100)		66 (100)	71 (100)
Able to help yourself	Much more	7 (9.6)	8 (9.2)	15 (9.4)	0.365	3 (4.5)	5 (6.9)
	More	24 (32.9)	21 (24.1)	58 (66.7)		20 (30.3)	11 (15.3)
	Same or less	42 (57.5)	58 (66.7)	100 (62.5)		43 (65.2)	56 (77.8)
	Total	73 (100)	87 (100)	160 (100)		66 (100)	72 (100)

(26.5% response rate), 182 patients completed baseline questionnaires, 152 completed the two-week questionnaires, 126 completed the questionnaires at four weeks, and 120 completed the six-week questionnaires. The critical point in the analysis was the two-week point, the point at which patients in Group A (intervention arm) had already received the SPARC intervention and patients in Group B (control arm) had not yet received the SPARC intervention. Seven patients did not complete the trial, citing questionnaire completion and taking part in the trial too burdensome as reasons for not continuing. Two patients expressed concern around issues of data collection and had anticipated more face-to-face contact visits as opposed to receiving postal questionnaires. At the end of the trial (eight weeks after completion of baseline questionnaires), 23 patients had died and 159 patients were alive. There was no significant difference in the number of deaths between the intervention and control groups. In Group A (intervention), nine people (10.3%) and in Group B (control), 14 people (14.7%) died within the eight-week study period. A summary of the recruitment is presented in Fig. 1.

Baseline Data

Of the 182 study participants, 84 were males (46.2%) and 98 were females (53.8%). The mean age of the participants on trial registration was

64.47 years (median 66.00 years; SD 12.57; minimum age 27 years; and maximum age 90 years). There were 87 (47.8%) participants in the intervention arm (Group A) and 95 (52.2%) participants in the control arm (Group B); there was no significant difference in the partnership status of patients in Group A vs. Group B. Most patients were married ($n = 118$; 64.8%) and of White-British ethnicity ($n = 173$; 95.1%). No significant differences were observed between the intervention and control groups with respect to age distribution, gender distribution, in the baseline scores for MYCAW, EQ-5D, and PEI, or in any other study parameters. Demographic characteristics of participants are summarized in Table 3.

MYCAW: Comparison of Groups From Baseline to Weeks 2, 4, and 6

The mean MYCAW Concern 1 score for both groups improved over six weeks (Table 4). The overall mean change in score from baseline to Week 2 was 0.368 (median 0; SD 1.39); from baseline to Week 4 was 0.430 (median 0; SD 1.66); and from baseline to Week 6 was 0.462 (median 0; SD 1.59). There were no significant differences (no detectable effect) between the control and intervention groups in the change in mean MYCAW 1 scores at two-, four-, or six-week follow-up.

There was, however, a significant difference in the rankings for the change in MYCAW Concern 1 score

Table 6
Continued

Week 2		Week 4				Week 6			
Total	P	Group A (Intervention)	Group B (Control)	Total	P	Group A (Intervention)	Group B (Control)	Total	P
13 (9.3)	0.693	1 (1.9)	1 (1.8)	2 (1.8)	0.781	2 (3.8)	6 (10.3)	8 (7.3)	0.607
38 (27.1)		19 (35.8)	19 (33.3)	38 (34.5)		17 (32.7)	15 (25.9)	32 (29.1)	
89 (63.6)		33 (62.3)	37 (64.9)	70 (63.6)		33 (63.5)	37 (63.8)	70 (63.6)	
140 (100)		53 (100)	57 (100)	110 (100)		52 (100)	58 (100)	110 (100)	
13 (13.8)	0.481	2 (3.8)	4 (7.1)	6 (5.5)	0.676	4 (8.0)	6 (10.3)	10 (9.3)	0.346
42 (31.6)		19 (35.8)	19 (33.9)	38 (34.9)		11 (22.0)	17 (29.3)	28 (25.9)	
78 (58.6)		32 (60.4)	33 (58.9)	65 (59.6)		35 (70.0)	35 (60.3)	70 (64.8)	
133 (100)		53 (100)	56 (100)	109 (100)		50 (100)	58 (100)	109 (100)	
9 (6.6)	0.989	1 (1.9)	3 (5.1)	4 (3.6)	0.995	3 (5.9)	5 (8.5)	8 (7.3)	0.884
43 (31.6)		16 (30.2)	14 (23.7)	30 (26.8)		13 (25.5)	13 (22.0)	26 (23.6)	
84 (61.8)		36 (67.9)	42 (71.2)	78 (69.6)		35 (68.6)	41 (69.5)	76 (69.1)	
136 (100)		53 (100)	59 (100)	112 (100)		51 (100)	59 (100)	110 (100)	
12 (9.4)	0.939	2 (3.8)	3 (5.6)	5 (4.7)	0.948	2 (4.1)	5 (8.9)	7 (6.7)	0.446
31 (24.4)		12 (23.1)	11 (20.4)	23 (21.7)		10 (20.4)	11 (19.6)	21 (20)	
84 (66.1)		38 (73.1)	40 (74.1)	78 (73.6)		37 (75.5)	40 (71.4)	77 (73.3)	
127 (100)		52 (100)	54 (100)	106 (100)		49 (100)	56 (100)	105 (100)	
8 (5.8)	0.507	1 (2.0)	1 (1.7)	2 (1.8)	0.445	2 (4.0)	3 (5.2)	5 (4.6)	0.319
26 (19.0)		9 (17.6)	7 (11.9)	16 (14.5)		4 (8.0)	9 (15.5)	13 (12.0)	
103 (75.2)		41 (80.4)	51 (86.4)	92 (83.6)		44 (88.0)	46 (79.3)	90 (83.3)	
137 (100)		51 (100)	59 (100)	110 (100)		50 (100)	58 (100)	108 (100)	
8 (5.8)	0.305	4 (7.0)	0 (0)	4 (3.6)	0.088	3 (6.3)	3 (5.2)	6 (5.7)	0.625
31 (22.5)		8 (15.1)	8 (14.0)	16 (14.5)		9 (18.8)	9 (15.5)	18 (17.0)	
99 (71.7)		41 (77.4)	49 (86.0)	90 (81.8)		36 (75.0)	46 (79.3)	82 (77.4)	
138 (100)		53 (100)	57 (100)	110 (100)		48 (100)	58 (100)	106 (100)	

(baseline to Week 2) of patients in Group A (intervention: mean rank of patients: 61.21) and Group B (control: mean rank of patients: 75.37) (Mann-Whitney $Z = -2.192$; $P = 0.028$; $n = 136$). Overall, patients in Group B (control) showed greater improvement or less deterioration in the MYCAW score than patients in Group A (intervention). The mean change in MYCAW Concern 1 score (baseline to Week 2) in Group A (intervention) was 0.15 (SD 1.32; median 0) (a small improvement) vs. Group B (control) 0.57 (SD 1.44; median 0). When the scores for changes in MYCAW Concern 1 score for the patients were recoded (baseline to Week 2) into groups for deterioration/no change/improvement, there was a statistically significant association between the change in MYCAW Concern 1 score and study arm ($\chi^2_{\text{trend}} = 5.51$; degrees of freedom = 1; $P = 0.019$). A higher proportion of patients in Group B (control: 34 of 70 [48.6%]) had an improvement in the MYCAW Concern 1 score (baseline to Week 2) compared with patients in Group A (intervention: 19 of 66 [28.8%]). A higher proportion of patients in Group A (intervention: 16 of 66; 24.2%) showed a deterioration in the MYCAW Concern 1 score (baseline to Week 2) compared with patients in Group B (control: 10 of 70; 14.3%). There was no significant difference in the rankings for the change in MYCAW Concern 1 score from baseline to Week 4 or from baseline to Week 6.

MYCAW Concerns at Baseline

Of the 182 patients completing baseline questionnaires, 173 (95.1%) respondents nominated and scored a primary concern and 125 (68.7%) nominated and scored a secondary concern. For both MYCAW primary and secondary concerns, physical symptoms, condition and disability predominated, but other concerns, such as apprehension for themselves or others, concerns about disease progression and dying, feelings of loss of function or purpose, and about help needed, also were prominent. Similarities were marked, in that for all groups, symptoms, condition, and disability featured most strongly. For cancer survivors, and those receiving end-of-life cancer care, all concerns were named: apprehension for themselves or others; concerns related to the progression of disease; psychological concerns; concerns related to loss or existential issues; concerns about needing help; the effect on their social life; work or financial issues; and treatment effects.

EQ-5D Variables: Comparison of Groups From Baseline to Weeks 2, 4, and 6

There were no meaningful or significant associations between any of the EQ-5D domains for Groups A (intervention) and B (control) at baseline, Weeks 2, 4, or 6. Table 5 shows the frequency of responses for the EQ-5D domains at all of the time points. It is

also worth noting that, in this analysis, the mean EQ-5D scores did not change in any significant or meaningful way.

PEI Scores: Comparison of Groups From Baseline to Weeks 2, 4, and 6

Table 6 shows the distribution of responses for the PEI questions at baseline and Weeks 2, 4, and 6, respectively, in Groups A (intervention) and B (control) and in the total sample (A+ B). There were no meaningful or significant associations between the PEI responses to the questions for either group or in the total sample at any of the time points.

Discussion

The unexpected negative finding that a higher proportion of patients in the control group (34 of 70; 48.6%) showed an improvement in their MYCAW score from baseline to Week 2 compared with the intervention group (19 of 66; 28.8%) ($P = 0.019$) raises questions about the application of SPARC and possibly other holistic needs assessment questionnaires in the context of a specialist palliative care service.

No positive effect of the intervention on either the primary or secondary outcome measures was observed at two, four, or six weeks, suggesting that the intervention did not have a detectable beneficial effect at any point and the difference between arms was obliterated when the control arm received SPARC.

Data that indicate that most patients felt that no particular action or benefit followed from completion of the SPARC will be reported elsewhere. There were no meaningful or significant differences between the control and intervention groups in the scores for health-related quality of life as recorded in the general measure EQ-5D. This measure did not significantly change over the six weeks, as would be expected of patients attending a palliative care service. However, in contrast, there appears to be improvement in the most important concern as recorded in the MYCAW; this suggests that usual palliative care is having a beneficial effect in this respect.

Results in the Context of Other Studies

Several other studies have examined the clinical utility of some holistic needs assessment tools. These tools include 1) Palliative Care Assessment Tool,^{35,36} 2) the Initial Health Assessment,³⁷ and 3) Needs at the End of Life Screening Tool.³⁸ Although the studies have measured changes in clinical outcomes after needs assessment, no controlled study has demonstrated an improvement in clinical or patient-reported outcomes as a result of the intervention. Although many of these studies demonstrated an

improvement in documentation of needs, uptake of findings and action after the assessment of needs have been described as poor, with no significant overall improvements in care outcomes. The reasons for these results are unclear but could be a result of inadequate power to detect a change; the tools not being comprehensive enough for holistic needs assessments; outcomes chosen may have been inappropriate; HCPs' attitudes, knowledge, or skills; and timing of and the availability/nonavailability of services.³⁸ It is also possible that standardized needs assessments will never supplement the quality of care unless properly integrated with the clinical methods and routine care planning procedures of the clinical team. Scandrett et al.³⁸ proposed that new methods to achieve practice change should be considered and evaluated when assessing such interventions.⁷

Limitations of the Study

Our poor recruitment of patients within the hospital support service meant our study sample had fewer patients with conditions other than cancer and a smaller proportion of patients acutely ill than the whole population of patients referred to the palliative care service.

The context of a specialist palliative care service is possibly the most difficult environment to test an assessment intervention in that the existing holistic needs assessments may be sufficient to detect all issues that require attention. The SPARC pilot trial focused primarily on outcomes, not on the processes involved in implementing the intervention. The Medical Research Council framework requires an evaluation of the pilot study, and a process evaluation is underway and will be reported elsewhere, to elucidate the precise mechanism by which this result came about.

Conclusions

This trial result identifies a potential negative effect of SPARC in specialist palliative care services, raising questions that standardized holistic needs assessment questionnaires may be counterproductive if not integrated with a clinical assessment that informs the care plan. It may raise expectations that are not subsequently met.

We can, however, conclude that a larger trial with more power to detect an effect is highly unlikely to be positive. A larger trial in specialist outpatient or home care services using the same design and outcome measures is unlikely to demonstrate any benefit. It is nevertheless possible that SPARC has utility for the original purpose for which it was designed, as a screening tool, in primary care or general

medical care for selection of patients who may benefit from a referral to specialist palliative care. It is also possible that, were SPARC to be included in the routine clinical assessment that informs a care plan within a specialist service, then immediate benefit might follow within an effective supportive or palliative care service.

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Supplementary Data

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